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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,367	10/30/2001	Barbara A. Brewitt	20371.0004c4	3277

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Ann W. Speckman
SPECKMAN LAW GROUP
Suite 100
1501 Western Avenue
Seattle, WA 98101

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/001,367	BREWITT, BARBARA A.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,11,13-28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 11, 13-28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendments and remarks filed on 11/27/06. Claims 1, 2, 9-11 and 13-30 were pending. Claims 9, 10 and 29 have been cancelled. Claims 31-33 have been added. Therefore, claims 1, 2, 11, 13-28 and 30-33 are currently pending and are examined. The Office notes the incorrect claim inclusion in the previous Office Action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

4. The allowability of the claims 24-28 is withdrawn.

5. The current status of claim 12 is not indicated in the claim listing.

Claim Rejections - 35 USC § 102(b) maintained

6. The rejection of claims 1, 11,and 14 under 35 USC § 102(b) as being anticipated over Antoniades et al. is maintained for reasons set forth in the Office Actions dated 8/24/04, 6/13/05 and 6/27/2006.

Applicant has amended claim 1 to remove the concentration of less than $1x10^{-6}$ M of IGF-1 limitation and added the homeopathic potencies of IGF-1. Applicant indicates that the composition of Antoniades et al. is directed to wound healing. Applicant argues that use of homeopathic potency of IGF-1 is not taught by Antoniades et al. Specifically, Applicant is arguing that there is no teaching or suggestion

whatsoever in Antoniades et al. that the compositions are prepared homeopathically to produce homeopathic potencies. It is argued that there is no description, either expressly or inherently, of homeopathic potencies, or of serial dilutions and serial successions. In addition, Applicant is arguing that no homeopathic nomenclature is used. Applicant's arguments have been fully considered but are not found to be persuasive because in the absence of a disclosure of a particular starting concentration of IGF-1 in claim 1 it is anticipated that the concentration disclosed by Antoniades et al. (IGF-1 of 500ng-1 μg) is included in the instant invention, regardless of the method used to prepare IGF-1 composition of the instant invention (The various homeopathic potencies could potentially include the concentration of IGF-1 disclosed in the instant invention). In addition, arguments relating to method of making were previously addressed in the Office Action dated of 6/27/2006 (pages 3-5), which have not been responded to by the Applicant in the instant response. Therefore, the rejection of record is maintained.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a.Claims 1, 2, 11, 13-28 and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

make and/or use the invention. Specifically, the specification does not reasonably provide enablement for a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 1, 2, 11, 13-28 and 30-33 are drawn to a preparation comprising homeopathic potency of purified IGF-1 suitable for oral administration. Applicant is clearly contemplating using very dilute concentration of the purified protein (pages 7 and 18). In the absence of a starting concentration of IGF-1, there is no guidance, which provide for the concentrations of the various homeopathic potencies contemplated for oral administration following the serial dilutions and serial successions. Although, 6X, 6C, 15X, 12C, 30C, 100C, 200C and 1M (1000C) potencies are art accepted, neither specification nor prior art teaches the starting concentration of the purified IGF-1 used in the preparation. The specification as filed is insufficient to enable one skilled in the art to

practice the claimed invention without an undue amount of experimentation because there is no teaching to indicate the starting concentration of IGF-1. The specification teaches (page 7) that homeopathic medicines are used at concentrations of micrograms (10^{-6} M) and nanograms (10^{-12} M). It also indicates that in other homeopathic preparations, the dilutions exceed avogadro's number 6.023 $x10^{-23}$. However, there is no guidance to teach one of skilled in the art to dilute purified IGF-1 to obtain the homeopathic potency of the instant invention (starting from what concentration!). Specifically, it does not teach the starting concentration of IGF-1, which is required to obtain the various homeopathic potencies of the instant invention. Further, given the physiological serum concentration of IGF-1 is 200ng/ml (Dunger et al. U.S. Patent No. 5, 466, 670) it is unclear if administering a homeopathic potency of IGF-1 will have any clinical relevance. Specifically, the specification does not teach any methods or working examples that would indicate that a preparation comprising homeopathic potency of purified IGF-1 suitable for oral administration in any subject for treatment.

In addition, regarding oral administration for treatment, variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. Further, there is no teaching in the specification that would indicate that a preparation comprising homeopathic potency of purified IGF-1 suitable for oral administration would have any clinical effect upon the administration. In addition, one skilled in the art would not be able to predict the effects of the homeopathic potency of purified IGF-1 administered orally. The purified IGF-1 may not otherwise reach the target cell or tissue because of its inability to penetrate tissues or

cells where its activity is to be exerted, it may be absorbed by fluids, cells and tissues where it has no effect, circulation into the target area may be insufficient to carry the antagonist, and a large enough local concentration may not be established (see Pettit et al.,). The specification provides insufficient guidance with regard to these issues and provides no working examples or evidence, which would provide guidance to one skilled in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. Thus, undue experimentation would be required of one skilled in the art at the time the invention was made to use a preparation comprising homeopathic potency of purified IGF-1 suitable for oral administration.

Further, there is no teaching in the specification with respect to the various pathologies associated with the various physiological disorders relating to IGF-1 caused by various etiologies. The usefulness of the compositions contemplated in the claims is tied to the usefulness of the homeopathic potency of purified IGF-1 in treating various physiological disorders. In addition, the specification and the prior art have not disclosed a role for homeopathic potency of IGF-1 in the treatment of various physiological conditions.

If one skilled in the art is not guided as to the pathology of the various physiological disorders treatable using purified IGF-1, then the skilled artisan is also not guided as to how to use a preparation comprising homeopathic potency of purified IGF-1 suitable for oral administration. Since, there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation to try various conditions that maybe treated by

using homeopathic potencies of purified IGF-1. In addition, because there are no working examples provided describing the treatment of various physiological disorders, which use IGF-1, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

In addition, there is no guidance provided for the mechanism associated with the various physiological that are treatable using homeopathic potency of IGF-1 recited in the claims. While mechanism is not required, it can allow extrapolation of enablement to non-exemplified embodiments. Since applicant has not provided any working examples to teach the use of a preparation comprising homeopathic potency of purified IGF-1 suitable for oral administration for treating a subject experiencing a physiological disorder either *in vitro* or *in vivo*, it would require an undue amount of experimentation to one of skill in the art to practice the invention as claimed.

Given the breadth of claims 1, 2, 11, 13-28 and 30-33 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

8. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art unit 1647,
February 20, 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud